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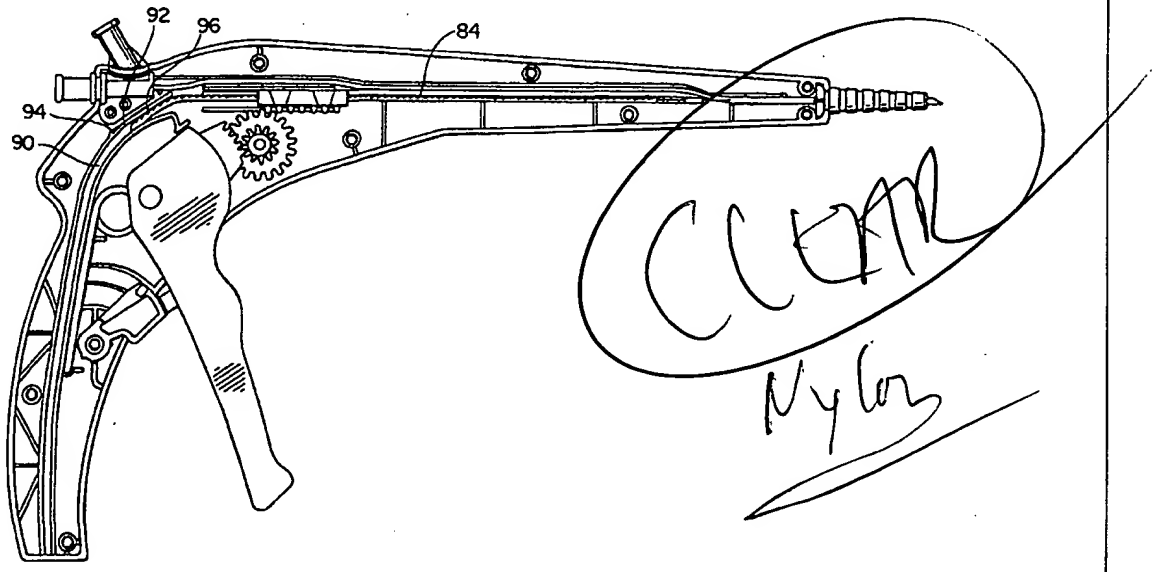

(57) Abstract

A stent delivery system for delivering a self-expanding stent to a predetermined location in a vessel includes a catheter body having an axial guidewire lumen and a pull-wire lumen. A medical device such as a self-expanding stent is held in a reduced delivery configuration for insertion and transport through a body lumen to a predetermined site for deployment. The stent is carried axially around the catheter body near its distal end and held in its reduced configuration by a retractable outer sheath. A proximal retraction handle is connected to the proximal end of the catheter body and includes a pistol grip trigger engaging a rachet mechanism, which is connected to a pull-wire which extends through the pull-wire lumen and is connected to the retractable outer sheath.

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Pull Back Stent Delivery System With Pistol Grip Retraction Handle

Background of the Invention

1. Field of the Invention

The present invention relates to an improved wire pull back delivery system. More specifically, the invention relates to a wire pull-back stent delivery system which utilizes a pistol grip retraction handle to retract the retractable outer sheath and deploy a medical implant for a minimally invasive application, such as an endovscular stent graft, vena cava filter, self-expanding stent, balloon expandable stent, or the like.

2. Description of the Related Art

Delivery system for deploying medical implants, such as an endovscular stent graft, vena cava filter, self-expanding stent, balloon expandable stent or the like, are a highly developed and well known field of medical technology. These medical devices have many well known uses and applications. In particular, a stent is a prosthesis which is generally tubular and which is expanded radially in a vessel or lumen to maintain its patency. Stents are widely used in body vessels, body canals, ducts or other body lumens. A self-expanding stent is a stent which expands from a compressed delivery position to its original diameter when released from the delivery device, exerting radial force on the constricted portion of the body lumen to re-establish patency. One common self-expanding stent is manufactured of Nitinol, a nickel-titanium shape memory alloy, which can be formed and annealed, deformed at a low temperature, and recalled to its original shape with heating, such as when deployed at body temperature in the body.

Wire pull-back stent delivery systems are disclosed in US 5360401 and US 5571135. One important factor in delivering the stent is a controlled precise retraction of the retractable outer sheath. What is needed is a wire pull-back stent delivery system which provides for a controlled and precise retraction of the retractable outer sheath and enables the physician to accurately determine proper positioning of the stent, as well as track the retraction of the outer sheath.

Summary of the Invention

The inventive stent delivery system for delivering a self-expanding stent to a predetermined location in a vessel includes a catheter body having an axial guidewire lumen and a pull-wire lumen. A medical device such as a self-expanding stent is held in a reduced delivery configuration for insertion and transport through a body lumen to a predetermined site for deployment. The stent is carried axially around the catheter body near its distal end and held in its reduced configuration by a retractable outer sheath. A proximal retraction handle is connected to the proximal end of the catheter body and includes a pistol grip trigger engaging a rachet mechanism, which is connected to a pull-wire which extends through the pull-wire lumen and is connected to the retractable outer sheath.

Brief Description of the Drawings

A detailed description of the invention is described below with specific reference being made to the drawings, in which:

Figures 1 and 2 are side views of the inventive stent delivery system;

Figure 3 shows the distal end of the inventive stent delivery system;

Figure 4 is a cross-sectional view of the catheter body taken along section line 4-4 of Figure 3;

Figure 5 is a cross-sectional view of the catheter body taken along section line 5-5 of Figure 3;

Figures 6-8 show details of Figure 3 in greater detail;

Figure 9 shows the connection of the pull-wire to the strip portion of the rachet mechanism;

Figure 10 shows the Y-luer;

Figure 11 shows one side of the two-piece snap fit proximal retraction handle with its components in place;

Figure 12 shows the other side of the two-piece snap fit proximal retraction handle with the strip retracted into a channel;

Figure 13 and 14 show the delivery system partially and fully deployed;

Figure 15 shows the flexible ratcheting pawl in more detail, and

Figures 16 and 17 show an alternate embodiment for attaching the pull-wire to the pull-ring.

Description of the Preferred Embodiment

While this invention may be embodied in many different forms, there are shown in the drawings and described in detail herein a specific preferred embodiment of the invention. The present disclosure is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiment illustrated.

Figures 1 and 2 show side views of the inventive delivery system. The preferred embodiment discussed below specifically discusses delivering a self-expanding stent, but it should be understood that the inventive delivery system can deliver any medical implant for a minimally invasive application, such as an endovascular stent graft, vena cava filter, self-expanding stent, balloon expandable stent or the like.

The preferred embodiment is a two-part system including an implantable medical device such as a self-expanding stent and a delivery catheter. The delivery catheter is shown generally at 10 and includes the catheter body 12, the retractable outer sheath 14 and the proximal retraction handle 16.

Figure 3 shows the distal end of the delivery system 10, and the retractable outer sheath 14 in more detail. A medical device is held in its delivery configuration by outer sheath 14, and in the preferred embodiment the medical device is a self-expanding stent 18 which is carried concentrically around the single lumen extrusion 35 near the distal tip 20.

Figure 4 shows that catheter body 12 is a tri-lumen catheter, and in the preferred embodiment is a nylon extrusion with a guidewire lumen 22, a stent flushing lumen (priming port) 24 and a pull-wire lumen 26. The guidewire lumen accommodates a .035 inch guidewire 28. The guidewire lumen 22 and stent flushing lumen 24 terminate at the point shown generally at 30, and a stainless steel pull-wire 32 is shown extending from the pull-wire lumen 26 and which attaches to a stainless steel ring 34 (best seen in Figure 6). A nylon single lumen (guidewire lumen) extrusion 35 is thermally lap welded to the catheter body 12 at point 30 and has a nylon extrusion which is thermally molded to the distal end of the nylon single guidewire lumen 35 and tapered to create smooth atraumatic tip 20.

Figure 5 shows a cross-section view of the single guidewire lumen extrusion 35 along section lines 5-5 of Figure 3.

In the preferred embodiement, tantalum radiopaque marker bands 36 and 38 are bonded to the single lumen extrusion 35 using cyanoacrylate adhesive, although it should be understood that marker bands 36 and 38 could be attached using other well known techniques such as weld swaging or crimp/swaging. Marker bands 36 and 38 are used in connection with an imaging procedure to aid in determining proper positioning of the stent in the body lumen. Although fluoroscopy is the most common imaging procedure typically employed, x-ray, MRI or any other well known imaging techniques may also be utilized. In the embodiment of Figure 3 marker bands 36 and 38 show the proximal and distal ends of the stent 18 as carried in its delivery configuration. An alternate embodiment may locate marker bands 36 and 38 to mark the proximal and distal ends of the stent 18 in its expanded position, which would have a slightly shorter length than the stent in its delivery configuration. A nylon band stent stop 40 is also bonded to the single lumen extrusion 35 and prevents the stent 18 from moving proximally along the single lumen extrusion 35 as the outer sheath 14 retracts, assisting in accurate stent placement. Stop 40 could also be attached using any standard technique, such as overmolding or ultrasonic welding.

In the preferred embodiment the retractable outer sheath 14 is a clear medical grade PTFE (polytetrafluoroethylene) extrusion which covers the distal 10-20 cm (depending on stent length) of the catheter body 12. However the outer sheath 14 could be made of any suitable fluropolymer material. A specific alternate embodiment could utilize a fluropolymer material which is transparent to visible light to enable the operator to directly view deployment in an endoscopic delivery procedure. Such materials are well known in the art. In the preferred embodiment self-expanding nitinol stents of from 6-14 mm in diameter and ranging from 20-100 mm in length can be accommodated. It should be understood that any type of self-expanding stent could be employed, although nitinol self-expanding stents are preferred. The retractable outer sheath 14 is connected to the proximal retraction handle 16 by stainless steel pull-wire 32 which is welded to stainless steel ring 34 (best seen in Figure 6). Ring 34 is swaged in place to the outer sheath 14 with tantalum radiopaque marker band 42. The distal

end of retractable outer sheath 14 is designed to flush fit with tip 20 to create a smooth profile. The proximal end of retractable outer sheath 14 is finished with a smooth transition consisting of a thermally molded nylon extrusion swaged in place with a tantalum radiopaque marker band 44 (best seen in Figure 7). It should be understood that tapered transition could be molded in place, which would eliminate the need for a marker band swaged in place to attach the nylong extrusion. It should also be understood that the marker band could be bonded or crimp/swaged. The tapered smooth transition of the proximal portion of outer sheath 14 allows catheter body 12 to be more easily extracted from the body lumen and introducer sheath. The proximal end of retractable outer sheath 14 slidably seals to catheter body 12 permitting it to slide proximally along catheter body 12 when retracted by pull-wire 32. The nitinol stent 18 is compressed at low temperature for loading into delivery system 10 and held in its reduced delivery configuration by retractable outer sheath 14. Upon deployment in vivo at body temperature the original stent shape is restored as the nitinol stent self-expands, exerting radial force on the constricted portion of the body lumen to re-establish patency. Marker band 45 is also bonded to extrusion 35 approximately one stent length proximally of marker band 42 (in the unretracted position) and is utilized to confirm full stent release as discussed further below. It should be understood that marker band 45 could also be attached using swaging or crimp/swaging.

Figures 6-8 show details of Figure 3 is more detail.

Referring again to Figures 1 and 2, the stent 18 is deployed using proximal retraction handle 16. Proximal retraction handle 16 is a multi-component assembly ergonomically designed with a pistol grip trigger 46. The trigger mechanism 46 is contained within a two-part molded ABS (acrylonitrile, butadiene, styrene) outer housing that is snap-fit together. The ABS trigger 46 has a polypropylene safety lock mechanism 48 to prevent inadvertent stent release. The proximal retraction handle 16 is connected to the catheter body 12 by the pull-wire 32, a Y-luer assembly shown generally at 50 and a strain relief 52.

Referring now to Figure 9, catheter body 12 is connected to strain relief 52, and the proximal end of pull-wire 32 exits from lumen 26 and is threaded and crimped to a strip 54 by crimp tube 56, which is part of the ratchet mechanism used to

retract outer sheath 14. Strain relief 52 is made of Pebax® and is insert molded over catheter body 12, and is constructed to fit inside the nose of proximal handle 16 (best seen in Figures 11 and 12).

Referring now to Figure 10, the Y-luer assembly 50 is shown, and consists of a nylon Y-luer with a nylon single lumen extrusion overmolded to each leg of the "Y". It should be understood that the extrusion could also be bonded to each leg of the "Y". Leg 58 of the "Y" forms the stent flushing port and leg 60 forms the guidewire port. Each single lumen is thermally lap welded to the catheter body 12 and provides communication between the Y-luer and the guidewire lumen 22 and the stent flushing lumen 24. The stent flushing lumen is used to fill the retractable outer sheath 14 with fluid to purge air out of the outer sheath 14 prior to insertion of the catheter body 12 into the body.

Referring now to Figure 11, the proximal retraction handle 16 is shown in more detail and is a multi-component assembly ergonomically designed with a pistol grip 46, which is engaged by trigger spring 62. The pistol grip 46 or trigger has two cylindrical protrusions 64 on either side of trigger 46 which extend outwardly and are received by pivot mounts molded into the proximal retraction handle 16 to attach the pistol grip 46 to the handle 16 as well as provide a point about which the pistol grip rotates. A trigger stop 66 defines the normal trigger position and the trigger 46 is maintained in this normal position by trigger spring 62. As the trigger 46 is squeezed it rotates to its compressed position, and when released the trigger spring forces the trigger to rotate back to its normal position flush with the trigger stop 66. Trigger 46 includes a pair of gear engaging members 68 which are spaced apart to form a channel wide enough to receive the larger gear 72 of gear 70. Gear 70 includes gear 72 and a pair of gears 74 fixedly attached on either side of gear 72. Gears 74 engage the gear engaging portions 68 of trigger 46 to rotate gear 70 as trigger 46 rotates. Axle 76 is received by molded mounts in the two parts of handle 16 to attach the gear to the handle 16. Gear 72 engages the ratchet mechanism which is attached to the pull-wire 32. The ratchet mechanism is comprised of a rack driver which is comprised of 2 parts, a rack 80 and a rack tab 82, which snap fit together to form a channel for receiving strip 84. As can be seen best in Figure 15, strip 84 contains ramp shaped stops 86, each adjacent pair of

stops forming detents 88 (best seen in Figure 15). Rack tab 82 contains a flexible ratcheting pawl 89 which engages with detents 88 such that when the rack driver is moved proximally when the trigger 46 is squeezed to its compressed position, strip 84 is moved proximally, but when the rack driver is moved distally when trigger 46 is rotated to its normal position, the flexible ratcheting pawl 89 slides up ramp shaped stop 86 to disengage from strip 84.

As is best shown in Figure 12, strip 84 is received by channel 90. A second spring, strip spring 92 is securely held to handle 16 by tail 94 and its locking head portion 96 lockingly engages with detents 88 to hold strip 84 in place when trigger 46 is released and rack tab 82 is moved distally to lockingly engage with the adjacent distal detent 88. The ramp shaped stops 86 (best seen in Figure 15) allow the strip to be moved proximally in channel 90 by rack tab 82 until the adjacent detent lockingly engages with strip spring 92. The detents are each approximately 2 mm apart so that each complete squeeze of the trigger 46 retracts the pull-wire 32 and outer sheath 14 approximately 20 mm. By repeatedly squeezing and releasing trigger 46 the outer sheath 14 is fully retracted to release the stent 18 to self-expand. The rachet mechanism is designed to work with any stent of lengths between 20 and 100 mm, although it could easily be designed to accept any desired length stent.

The ratio of gear 70 in the embodiment shown in Figure 12 is 2:1, such that a 1 mm squeeze on trigger 46 retracts the outer sheath 2 mm. However, it should be understood that any desired gear ratio could be utilized. For example gear 70 is designed optionally to allow for a gear ratio of 1:1. In that embodiment a trigger 46 with a single gear engaging portion 68 is designed to engage gear 72, rather than gears 74, to provide a 1:1 ratio such that a 1 mm squeeze on the trigger will retract the outer sheath 14 1 mm. In order to accommodate this detents 88 would be spaced approximately 1 mm apart on strip 84 and it should be understood that the stops 86 and detents 88 could be arranged in any desired spacing. Gear 70 could also be designed if desired to have a ratio of 1:2, such that a 2 mm squeeze of trigger 46 retracts outer sheath 14 1 mm.

In operation, pre-placement imaging or other standard procedure is normally performed to identify an insertion tract and assess the site. A guidewire (.035

inch diameter in the preferred embodiment) 28 is maneuvered through the tract. The delivery system 10, with the preloaded medical device (a self-expanding stent in the preferred embodiment) is then passed through an introducer sheath and tracked over the guidewire until the medical device is positioned as desired. In the preferred embodiment markers 36 and 38 are used with standard imaging techniques such as fluoroscopy, x-ray, MRI or the like to aid in proper positioning of the stent 18 across the stricture. As the trigger 46 is repeatedly squeezed, the outer sheath 14 is retracted proximally to release the stent to self-expand. To aid in confirming complete stent deployment and release the operator observes marker 42 move to meet marker 45.

Figures 3, 13 and 14 show the distal ~~end of delivery system 10 in a pre-~~ deployed state (Figure 3), partially deployed state (Figure 13) and fully deployed state (Figure 14).

Referring now to Figures 16 and 17, an alternate embodiment of the inventive delivery system is shown where the pull-wire 32 is U-shaped with the U loop portion 100 of the pull-wire 32 looping around a notch 102 in the pull-ring 34. The 2 ends of the U-shaped pull-wire extend through pull-wire lumen 26 to attach to the ratchet mechanism. As shown in Figure 17, if desired a plurality of pull-wires 32 could by looped around a plurality of notches 102 spaced around pull-ring 34. A second pull-wire lumen could be provided to carry one or more pull-wires 32 to allow the pull-ring to be retracted with the pulling force more evenly distributed around the pull-ring perimeter. Two U-shaped pull-wires 32, each carried by a separate lumen and each looping around pull-ring 34 as shown in Figure 17 would provide 4 points arranged around pull-ring 34 to more evenly distribute the pulling force on the pull-ring. Each pull-wire lumen could also optionally carry more than 1 pull-wire to provide as many attachment points on pull-ring 34 as desired.

This completes the description of the preferred and alternate embodiments of the invention. It is to be understood that even though numerous characteristics and advantages of the present invention have been set forth in the foregoing description, together with the details of the structure and function of the invention, the disclosure is illustrative only and changes may be made in detail, especially in matters of shape, size and arrangement of parts within the principals of the

invention, to the full extent indicated by the broad, general meaning of the terms in which the appended claims are expressed. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which are intended to be encompassed by the claims attached hereto.

WHAT IS CLAIMED IS:

1. A delivery system for delivering a medical device to a predetermined location in a body lumen, the delivery system comprising:

a catheter body having proximal and distal ends, the catheter body having an axial guidewire lumen and a pull-wire lumen, the catheter body for transporting a medical device to a predetermined site in a body lumen for deployment;

a medical device having proximal and distal ends carried by the catheter body near the distal end;

a retractable outer sheath having proximal and distal ends and surrounding the medical device and containing the medical device in a delivery configuration where the medical device has a reduced radius along its entire axial length;

a proximal retraction handle connected to the proximal end of the catheter body, the handle including a pistol grip trigger engaged with a rachet mechanism, the ratchet mechanism being connected to a pull-wire, the pull-wire extending through the pull-wire lumen to the distal end of the catheter body where it is connected to the retractable outer sheath,

whereby the medical device is delivered by squeezing the pistol grip trigger, which causes the ratchet mechanism to retract the pull-wire, which retracts the retractable outer sheath, enabling deployment.

2. The delivery system of claim 1 wherein the medical device is a self-expanding stent.

3. The delivery system of claim 1 wherein the medical device is a balloon expandable stent.

4. The delivery system of claim 1 wherein the medical device is a vena cava filter.

5. The delivery system of claim 1 wherein the medical device is a endovascular stent graft.

6. The delivery system of claim 1 wherein

the ratchet mechanism is comprised of:

a rack driver comprised of a rack tab connected to a rack, the rack tab and rack constructed and arranged to form a through channel in the rack driver, the rack being further constructed and arranged to engage the gear;

an elongate strip having top and bottom sides and proximal and distal ends, the strip extending through the channel in the rack driver, the distal end of the strip being connected to the pull-wire, the top side of the strip further including a plurality of stops spaced apart on the strip to form a detent between each pair of adjacent stops, the stops being constructed and arranged such that the detents are each spaced a predetermined distance apart, and

the rack driver further including a flexible ratcheting pawl which is constructed and arranged to lockingly engage with a detent on the strip such that as the rack driver is moved proximally the strip is moved proximally, but when the rack driver is moved distally the pawl disengages from the strip to permit the rack driver to move distally without movement of the strip distally;

the ratchet mechanism interacting with a strip spring and a trigger spring to retract the pull-wire proximally;

the strip spring being connected to the proximal retraction handle and further including a locking portion which is constructed and arranged to lockingly engage with a detent of the strip to prevent the strip from moving distally, but which disengages with the strip to permit the strip to move proximally;

the trigger spring being connected to the proximal retraction handle and the trigger, the trigger spring having an open normal position and a compressed position, the trigger spring moving the trigger from the compressed position to the normal position when a squeezing force moving the normally open trigger to its compressed position is released;

whereby each complete squeeze of the pistol grip trigger rotates the gear engaging portion of the trigger, which rotates the gear and causes the rack driver and strip to move proximally a predetermined distance until the strip spring lockingly engages with the distally adjacent detent on the strip, retracting the outer sheath a predetermined distance and locking the strip spring to prevent the outer sheath from moving distally, and wherein upon release of the trigger the trigger spring moves the trigger to its normally open position, causing the rack driver to move distally a predetermined distance while the strip remains stationary, and where repeatedly

squeezing the trigger retracts the outer sheath over the entire axial length of the medical device to fully deploy the medical device.

7. The delivery system of claim 6 wherein the pull wire is connected to a pull ring which is connected to the retractable outer sheath.

8. The delivery system of claim 7 wherein the medical device is a self-expanding stent and further including:

first and second radiopaque marker bands connected to the catheter body at the distal end and respectively positioned near the distal and proximal ends of the stent, and which are utilized to position the stent at the desired position in the body lumen;

a stent stop connected to the catheter body just proximally of the stent for preventing the stent from moving proximally when the outer sheath is retracted and wherein the pull ring is connected to the outer sheath just proximally of the stent stop;

a third radiopaque marker band connected to the outer sheath and positioned over the pull ring;

a fourth radiopaque marker band connected to the catheter body approximately the axial length of the stent proximally of the pull ring,

whereby full release of the stent may be determined by observing the third radiopaque marker band move proximally until it reaches the fourth radiopaque marker band.

9. The stent delivery system of claim 8 wherein the pull wire lumen terminates just proximally of the fourth radiopaque mark band and the pull wire extends above the guide wire lumen portion of the catheter body to connect to the pull ring.

10. The stent delivery system of claim 9 wherein the proximal end of the retractable sheath is tapered and slidably seals to the catheter body proximally of the point where the pull wire emerges from the pull-wire lumen.

11. The stent delivery system of claim 10 wherein the distal end of the catheter includes a smooth tapered atraumatic tip surrounding the guide wire lumen and where the retractable outer sheath abuts the tip when in a fully unretracted position to create a stent containment compartment.

12. The stent delivery system of claim 11 including a stent flushing lumen which opens axially into the stent containment compartment to permit the stent containment

compartment to be purged of air by filling the stent containment compartment with fluid prior to introducing the stent delivery system into the body lumen.

13. The delivery system of claim 6 wherein the gear has a 2 to 1 ratio such that a 1 mm movement of the trigger retracts the outer sheath 2 mm, where the detents are located approximately 2 mm apart and where a complete squeeze of the trigger will retract the outer sheath approximately 20 mm.

14. The delivery system of claim 6 wherein the gear has a 1 to 1 ratio such that a 2 mm movement of the trigger retracts the outer sheath 2 mm, where the detents are located approximately 2 mm apart and where a complete squeeze of the trigger will retract the outer sheath approximately 10 mm.

15. The delivery system of claim 6 wherein the gear has a 1 to 2 ratio such that a 2 mm movement of the trigger retracts the outer sheath 1 mm, where the detents are located approximately 1 mm apart and where a complete squeeze of the trigger will retract the outer sheath approximately 5 mm.

16. The delivery system of claim 7 further including a second pull-wire lumen, each pull-wire lumen carrying at least one U-shaped pull-wire, where the legs of the at least one U-shaped pull-wire are connected to the ratchet mechanism and where a U loop portion of the at least one U-shaped pull-wire is looped through two attachment points on the pull ring, whereby retraction of the outer sheath is accomplished by having the pull-wires connected at a plurality of points on the pull ring to more evenly distribute the pulling force on the pull ring.

17. The delivery system of claim 7 further including a second pull-wire lumen and a second pull-wire connected to the ratchet mechanism, each pull-wire forming a U-shape with a U loop portion of the pull-wire looped through two attachment points on the pull ring and the 2 leg sections of the U-shaped pull-wire extending through the pull-wire lumen to attach to the ratchet mechanism, whereby retraction of the outer sheath is accomplished by having the pull-wires connected at four points on the pull ring.

18. The delivery system of claim 1 wherein the retractable outer sheath is made of a fluropolymer material which is transparent to visible light.

19. A delivery system for delivering a medical device to a predetermined location in a body lumen, the delivery system comprising:

a catheter body having proximal and distal ends for transporting a medical device to a predetermined site in a body lumen for deployment;

a medical device having proximal and distal ends carried by the catheter body near the distal end, and

a retractable outer sheath having proximal and distal ends and surrounding the medical device and maintaining the medical device in a delivery configuration where the medical device has a reduced radius along its entire axial length, wherein the proximal end of the retractable outer sheath is tapered to form a smooth atraumatic transition between the retractable outer sheath and the catheter body which aids in extraction of the delivery system from a body lumen.

20. A delivery system for delivering a medical device to a predetermined location in a body lumen, the delivery system comprising:

a catheter body having proximal and distal ends for transporting a medical device to a predetermined site in a body lumen for deployment;

a medical device having proximal and distal ends carried by the catheter body near the distal end;

a first radiopaque marker band carried by the catheter body and positioned proximally on the catheter body approximately the axial length of the medical device;

a retractable outer sheath having proximal and distal ends and surrounding the medical device and maintaining the medical device in a delivery configuration where the medical device has a reduced radius along its entire axial length;

the retractable outer sheath further including a second radiopaque marker band at its distal end.

whereby delivery of the medical device is confirmed by observing the second radiopaque marker band move to meet the first radiopaque marker band, indicating that the retractable outer sheath is fully retracted to delivery the medical device.

21. A stent delivery system for delivering a self-expanding stent to a predetermined location in a body lumen, the stent delivery system comprising:

a catheter body having proximal and distal ends, the catheter body having an axial guidewire lumen and a pull-wire lumen;

a self-expanding stent having proximal and distal ends concentrically arranged around the catheter body near the distal end;

a retractable outer sheath having proximal and distal ends and surrounding the self-expanding stent and maintaining the stent in a delivery configuration where the stent has a reduced radius along its entire axial length;

a proximal retraction handle connected to the proximal end of the catheter body, the handle including a pistol grip trigger having a gear engaging portion, a gear engaged with the gear engaging portion of the pistol grip trigger, and a ratchet mechanism engaged with the gear, the ratchet mechanism being connected to a pull-wire, the pull-wire extending through the pull-wire lumen to the distal end of the catheter body where it is connected to the retractable outer sheath,

whereby the stent is delivered by squeezing the pistol grip trigger, which engages the gear, the gear engaging the ratchet mechanism and retracting the pull-wire, which retracts the retractable outer sheath, releasing the stent to self-expand.

22. A method for delivering a medical device to a predetermined location in a body lumen, comprising the steps of:

providing the delivery system of claim 1;

moving the distal end of the catheter body to a delivery site;

delivering the medical device by retracting the retractable outer sheath which releases the medical device.

23. The method of claim 22 further including the step of filling the outer sheath with fluid to purge air prior to implantation.

24. A method for delivering a medical device to a predetermined location in a body lumen, comprising the steps of:

providing a stent delivery system including a self-expanding stent arranged around the distal end of a catheter body and maintained in its reduced diameter delivery configuration by a retractable outer sheath, the catheter body including a radiopaque marker band positioned approximately one stent length proximally of the stent, and where the distal end of the retractable outer sheath includes a radiopaque marker band;

inserting the distal end of the catheter body into a body lumen and moving the distal end of the catheter body to a delivery site;

retracting the outer sheath and confirming full deployment by observing under imaging the radiopaque marker band on the distal end of the retractable outer sheath moving to meet the radiopaque marker band positioned approximately one stent length proximally of the stent,

whereby when the marker bands meet confirmation is provided to the user that the stent is fully released to self-expand.

25. The method of claim 24 further including the step of filling the outer sheath with fluid to purge air prior to implantation.

Fig. 1

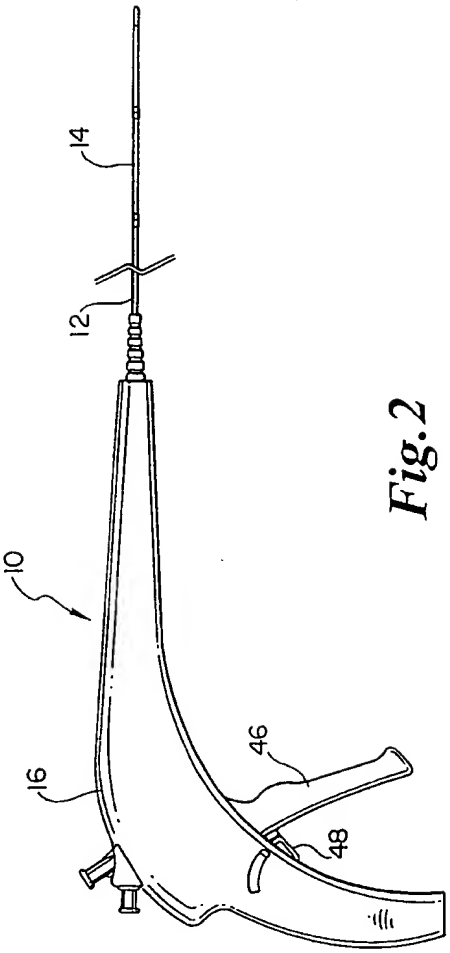
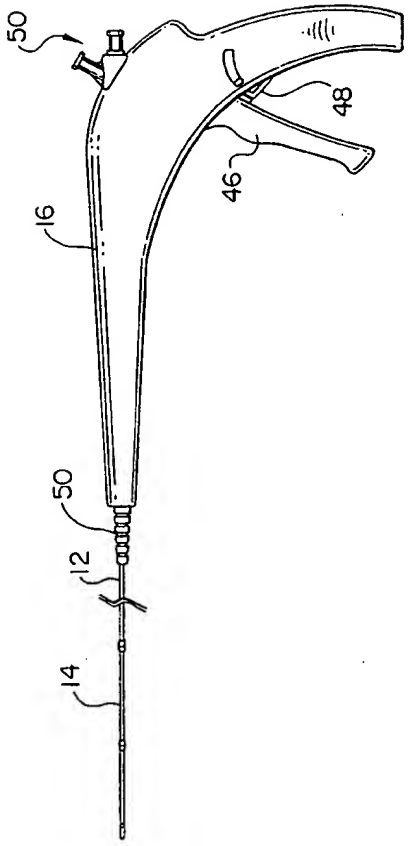
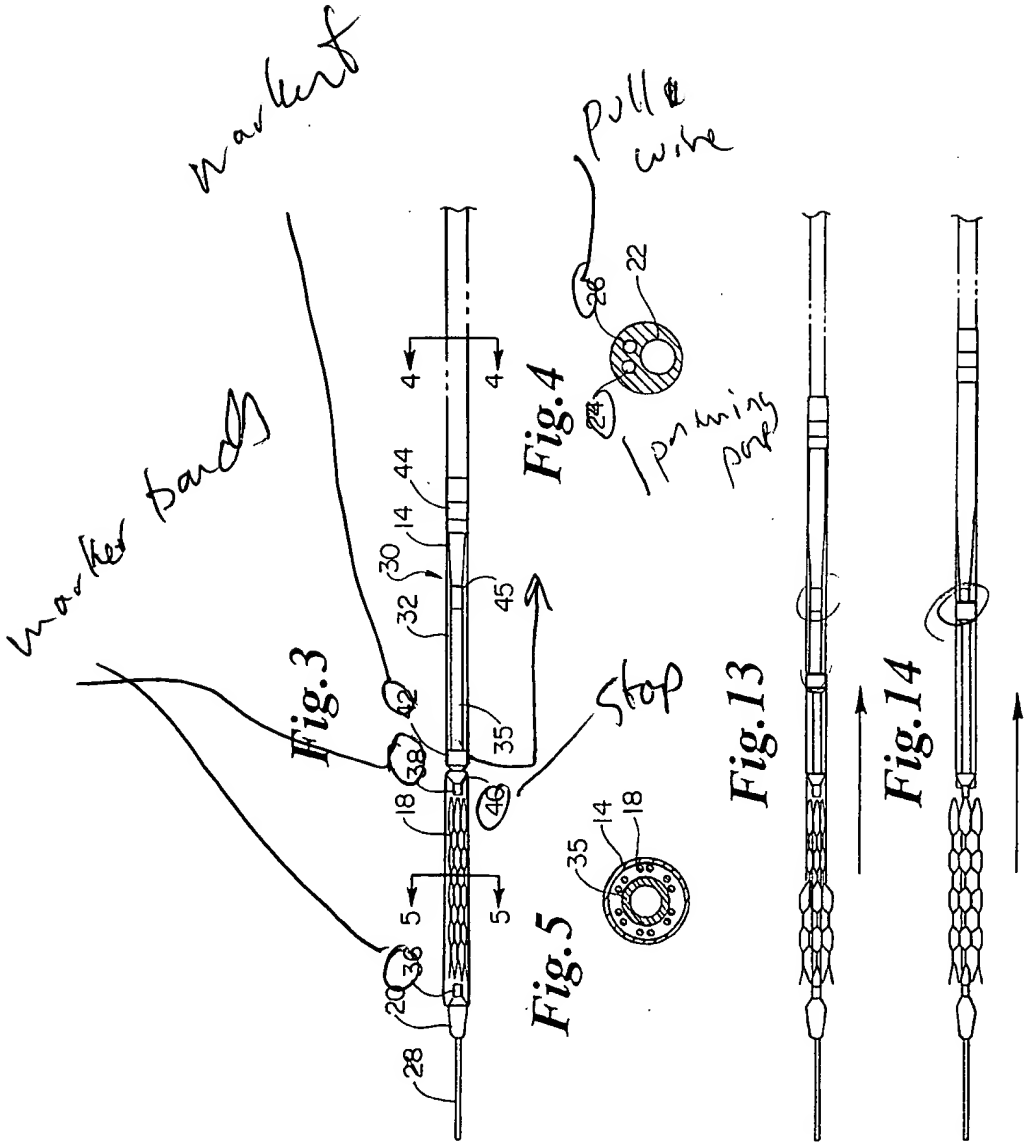


Fig. 2



42 ⇒ 45


marker bands
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4
44
14
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38
18
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28
Fig.3
pull wire
26
22
24
Fig.4
Stop
35
14
18
Fig.5
Fig.13
Fig.14

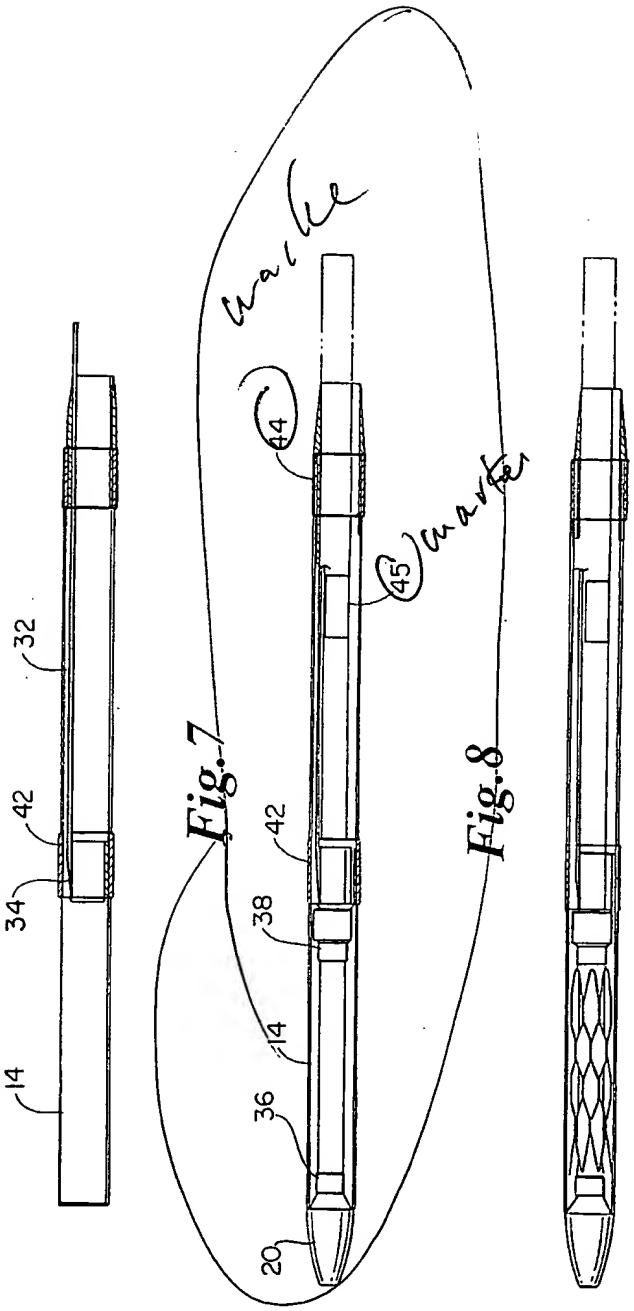
32
42
34
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Fig.6
Curve
44
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Curve
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Fig.7
Fig.8

Fig.10

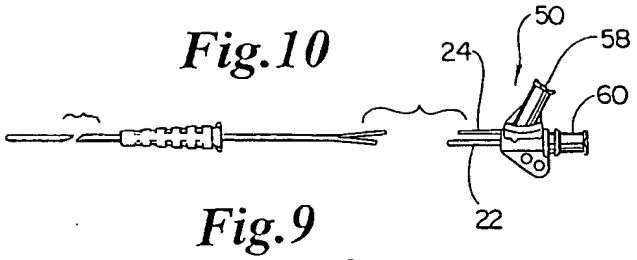


Fig.9

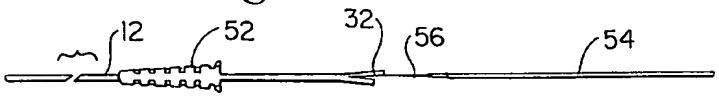
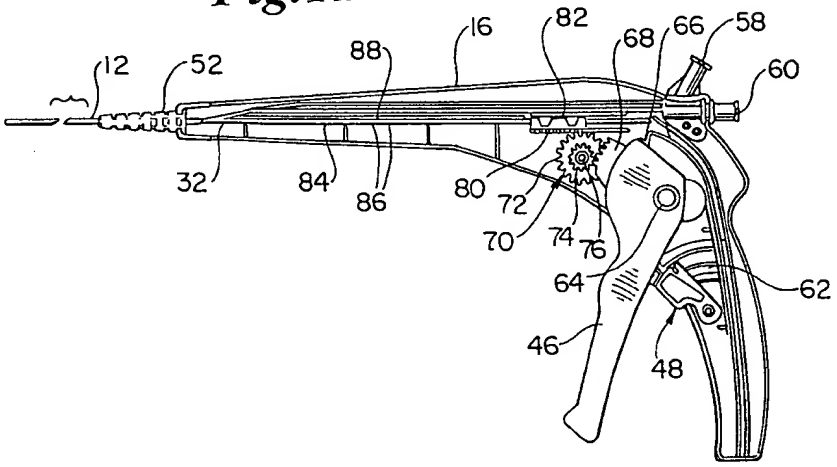


Fig.11



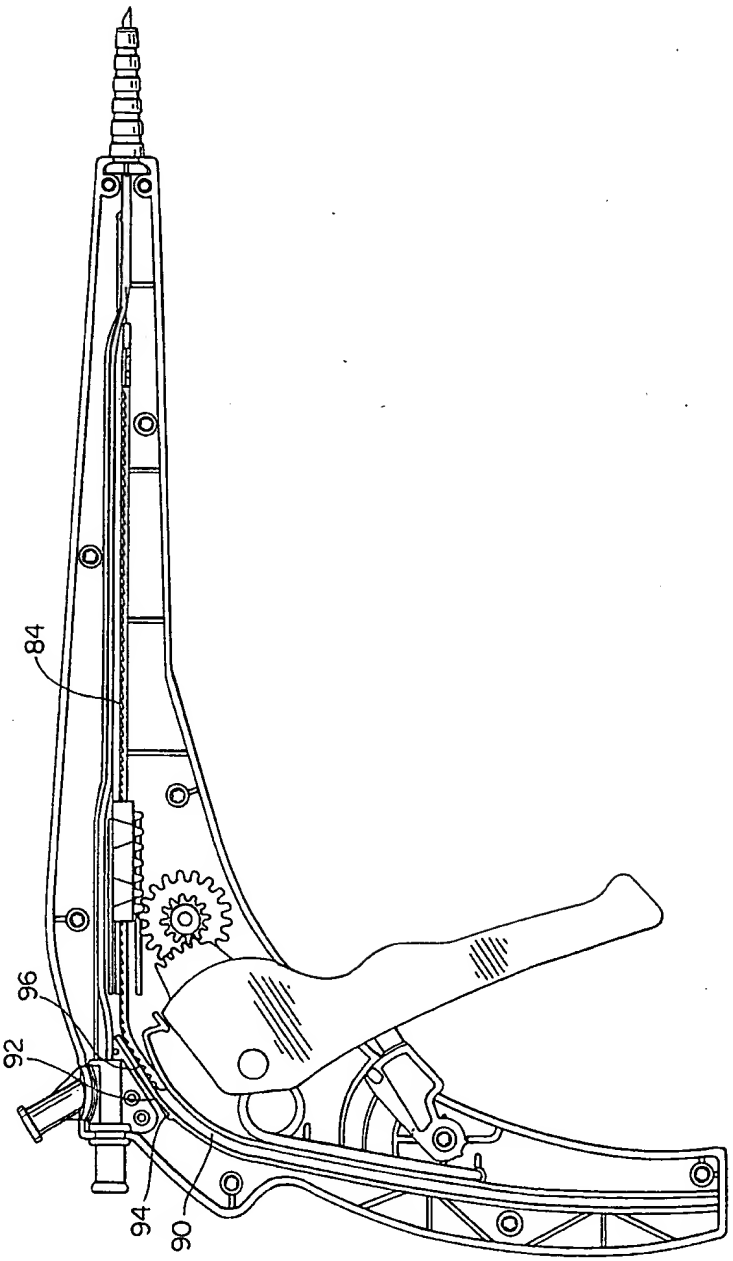


Fig.12

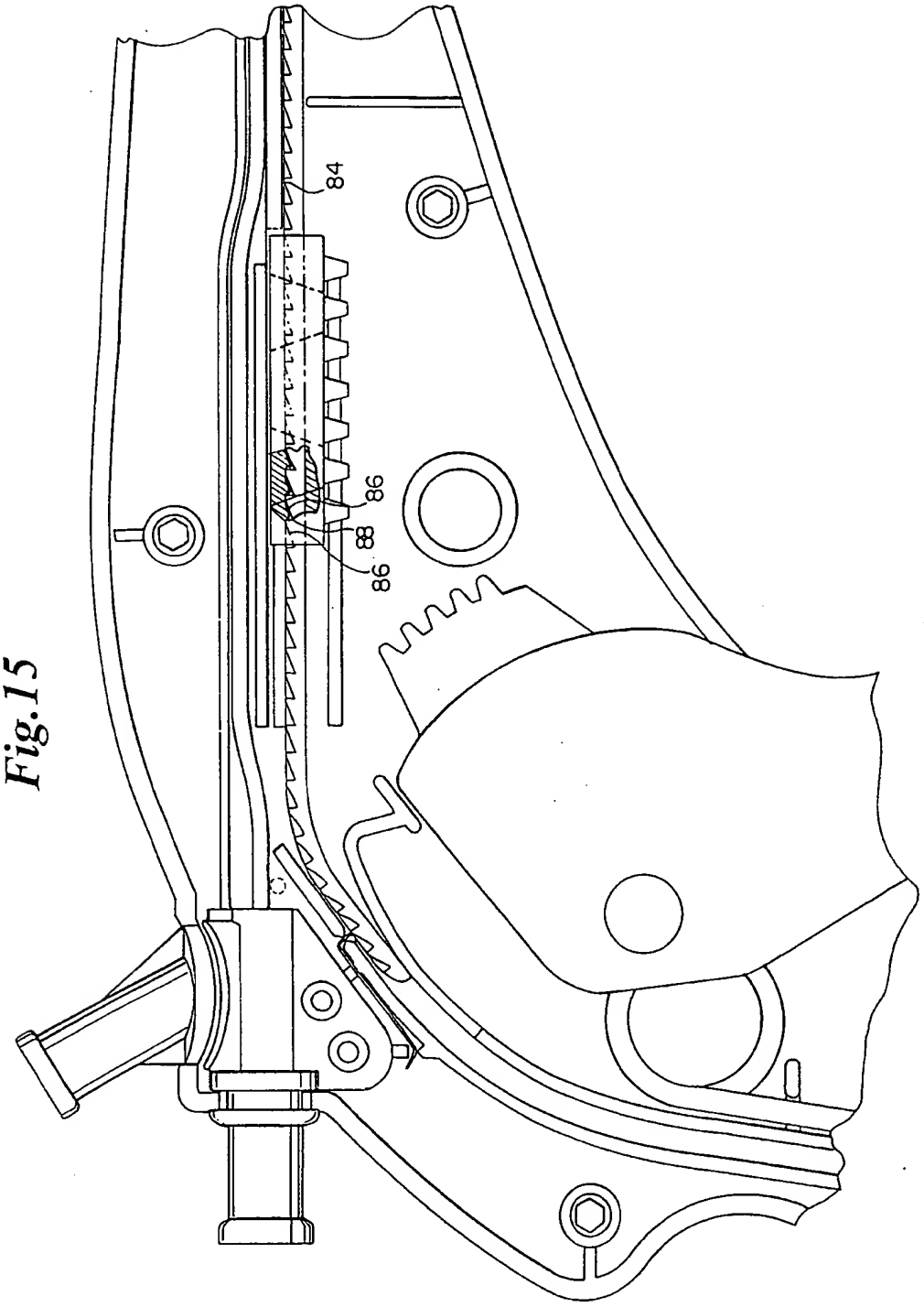


Fig.15

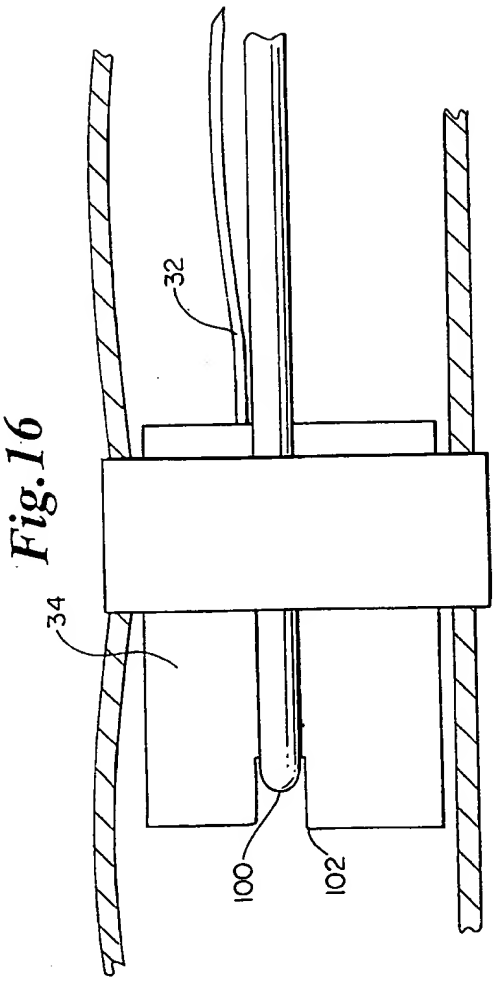


Fig. 16

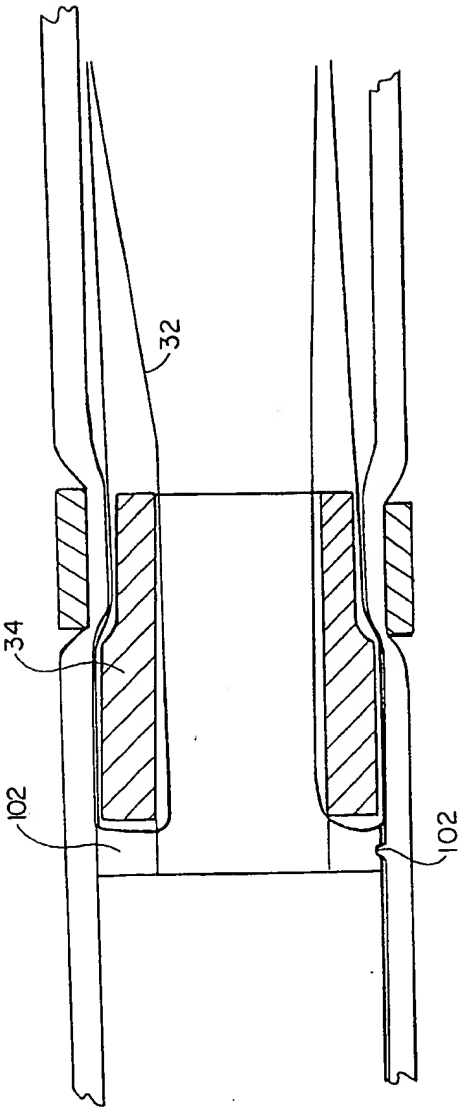


Fig. 17

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(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SciMed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventors: SULLIVAN, Roy, III; 23 Meaghan Way, Millville, MA 01529 (US). DEVRIES, Robert, B.; 22 Brady Way, Marlborough, MA 01752 (US).

(74) Agent: ARRETT, Richard, A.; Vidas, Arrett & Steinkraus, Suite 2000, 6109 Blue Circle Drive, Minnetonka, MN 55343-9131 (US).

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Published
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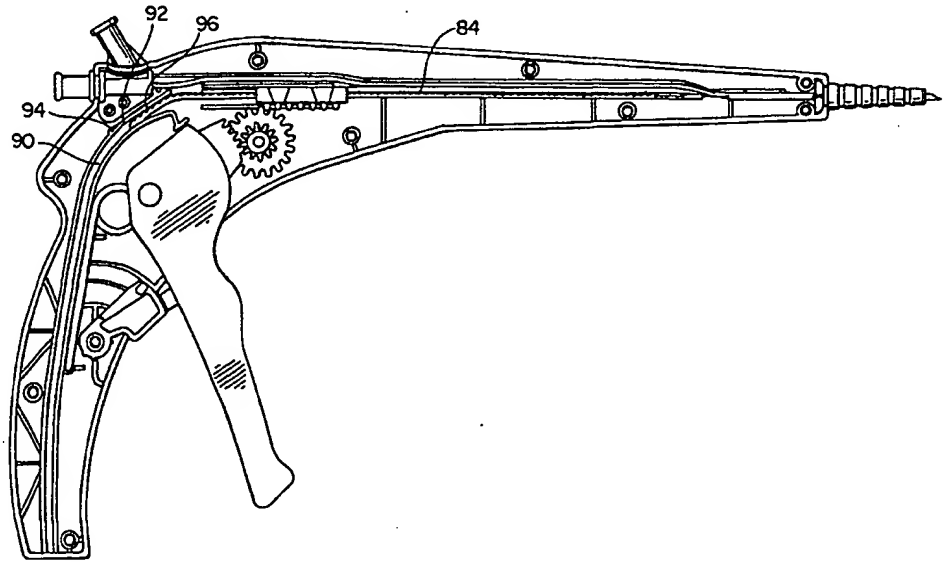
15 October 1998 (15.10.98)

(54) Title: PULL BACK STENT DELIVERY SYSTEM WITH PISTOL GRIP RETRACTION HANDLE



(57) Abstract

A stent delivery system for delivering a self-expanding stent to a predetermined location in a vessel includes a catheter body having an axial guidewire lumen and a pull-wire lumen. A medical device such as a self-expanding stent is held in a reduced delivery configuration for insertion and transport through a body lumen to a predetermined site for deployment. The stent is carried axially around the catheter body near its distal end and held in its reduced configuration by a retractable outer sheath. A proximal retraction handle is connected to the proximal end of the catheter body and includes a pistol grip trigger engaging a rachet mechanism, which is connected to a pull-wire which extends through the pull-wire lumen and is connected to the retractable outer sheath.

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INTERNATIONAL SEARCH REPORT

Int .tional Application No
PCT/US 97/20589

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 627 201 A (SCHNEIDER (EUROPE) AG) 7 December 1994 see the whole document ---	1,21
A	EP 0 518 838 A (AMS MEDINVENT S.A.) 16 December 1992 see the whole document ---	1,21
A	US 5 209 730 A (SULLIVAN) 11 May 1993 see abstract; figures ---	20
A	WO 95 21593 A (STENTCO, INC.) 17 August 1995 -----	

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Date of the actual completion of the international search	Date of mailing of the international search report
28 July 1998	11.08.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

INTERNATIONAL SEARCH REPORT

...ernational application No.
PCT/US 97/20589

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 22-25
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [X] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

1-18,20,21

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

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[ ] The additional search fees were accompanied by the applicant's protest.

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-18, 21

   A delivery system with a ratchet mechanism attached to a pull wire for delivering a medical device in a body lumen.

2. Claim : 19

   A delivery system with a tapered outer sheath for delivering a medical device in a body lumen.

3. Claim : 20

   A delivery system with a radiopaque maker for delivering a medical device in a body lumen.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ıtional Application No
PCT/US 97/20589

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 627201 A	07-12-1994	AU 659975 B	01-06-1995
		AU 6343794 A	15-12-1994
		JP 7051384 A	28-02-1995
EP 518838 A	16-12-1992	SE 503249 C	29-04-1996
		AT 128849 T	15-10-1995
		AU 650542 B	23-06-1994
		AU 1823592 A	17-12-1992
		CA 2071120 A	15-12-1992
		DE 9207942 U	26-11-1992
		DE 69205340 D	16-11-1995
		DE 69205340 T	18-04-1996
		ES 2078021 T	01-12-1995
		IE 69545 B	18-09-1996
		JP 6197984 A	19-07-1994
		SE 9101841 A	15-12-1992
		US 5591172 A	07-01-1997
		US 5759186 A	02-06-1998
US 5209730 A	11-05-1993	NONE	
WO 9521593 A	17-08-1995	US 5443477 A	22-08-1995
		US 5591196 A	07-01-1997
		AU 1918295 A	29-08-1995
		CA 2182721 A	17-08-1995
		EP 0744930 A	04-12-1996
		JP 9512182 T	09-12-1997
		US 5618300 A	08-04-1997
		US 5695517 A	09-12-1997